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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/211,507 | 12/14/1998 | ALAN R. HIRSCH | 054012-0009 | 9827 |

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EXAMINER

TATE, CHRISTOPHER ROBIN

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| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 06/24/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/211,507

Applicant(s)

Hirsch

Examiner

Christopher Tate

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 3, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-6, 9-11, 35, and 39-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 9-11, 35, and 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment filed is acknowledged and has been entered. Claims 1, 2, 4-6, 9-11, 35, and 39-44 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 112

Claims 1, 2, 4-6, 9-11, 35, and 39-44 stand rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office action which are restated below.

The specification, while being enabling for a method of increasing and/or decreasing blood flow to the vagina via inhaling the particular commercial odorants (see, e.g., page 12, lines 1-13 of the instant specification) and/or mixtures thereof instantly demonstrated, does not reasonably provide enablement for a method of increasing and/or decreasing blood flow to the vagina via inhaling any undefined odorant therein and/or the subjective odorants instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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Based upon Applicant's response and Declaration of July 6, 2001, it is deemed that Applicant has reasonably demonstrated that the particular commercial odorants (see, e.g., page 12, lines 1-13 of the instant specification) act to alter blood flow to the vagina via inhaling an effective amount thereof. However, the claims encompass such unusual use via inhaling any undefined odorant and/or the subjective odorants instantly claimed which is clearly beyond the scope of the instantly disclosed invention. The instantly claimed odorants are highly subjective with respect to the actual odors being encompassed and, thus, are not enabled - e.g., based upon the ingredients within a given recipe of pumpkin pie or banana nut bread, numerous distinct odors particular to that given recipe would be emitted therefrom. This is also the case for baby powder, which is actually talc to which a particular perfume is added and which varies by commercial manufacturer; and is also the case for cucumber (e.g., based upon the brand, species, age/ripeness, geographic location in which it is grown, etc.), licorice-based odorants (e.g., Good and Plenty® candy has a distinct odor from that of some other licorice based products such as anise), chocolate (e.g., milk chocolate has a distinct odor from dark chocolate), cherry odorants (e.g., cherry pie has an odor distinctly different from cherry cough drops), charcoal barbecue smoke odorant is exceptionally ambiguous as this could potentially be defining numerous distinct odors (what actually is a charcoal barbecue smoke odor - e.g., is it smoked barbecued meat odor, smoked barbecue sauce containing various spices, or something else?). In addition, it is noted in several instances that using the same odorant or mixture of odorants that cause an increased blood flow to the vagina to some females also cause a decrease in blood flow to the vagina in

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other females. Further, as disclosed by Doty (Philadelphia Sensorics, 1983), there are numerous variables such as an individual's occupation, general health, psychological state, and age which play a role in assessing sensory function of smell (see, e.g., pages 16-18). Therefore, altering blood flow to the vagina via the inhalation of such odorants, including the undefined and/or broadly defined odorants instantly claimed, as well as any undefined amounts thereof, is considered to be highly unpredictable between females based upon such variables.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use an odorant having the unusual disclosed/claimed functional effect, other than inhaling one of the particular demonstrated commercial odorants or mixtures thereof, in an amount effective to provide the claimed alteration in blood flow to the vagina.

Applicant's arguments have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicant argues that the odorants recited in the claims are clear in their meaning and the present disclosure of their commercial sources and working example is more than adequate for enablement. However, although the instantly disclosed particular commercial odorants and mixtures thereof are enabled, undefined and/or non-commercial subjective odorants - including mixtures thereof - are not for the reasons set forth above.

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Claims 1, 2, 4-6, 9-11, 35, and 39-44 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office action which are restated below.

The metes and bounds of the undefined or subjective odorants recited in claims 1, 2, 4-6, 9-11, 35, and 39-44 are not clearly nor adequately delineated making the claims unclear. For example, based upon the ingredients within a given recipe of pumpkin pie or banana nut bread, numerous distinct odors particular to that given recipe would be emitted therefrom. This is also the case for baby powder, which is actually talc to which a particular perfume is added and which varies by commercial manufacturer; and is also the case for cucumber (e.g., based upon the brand, species, age/ripeness, geographic location in which it is grown, etc.), licorice-based odorants (e.g., Good and PlentyTM has a distinct odor from that of some other licorice based products such as anise or other products having licorice as a base in combination with other ingredients), chocolate (e.g., milk chocolate has a distinct odor from dark chocolate), cherry (e.g., cherry pie has an odor distinctly different from cherry cough drops), charcoal barbecue smoke odorant is exceptionally ambiguous as this could potentially be defining numerous distinct odors (what actually is a charcoal barbecue smoke odor - e.g., is it smoked barbecued meat odor, smoked barbecue sauce containing various spices, or something else?). The subjective nature of the recited odorants (any of which is deemed essential in terms of adequately defining these particular active ingredients within the claimed article of manufacture) causes these claims to be very ambiguous and unclear.

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Claims 10 remains vague and indefinite by the phrase "wherein the concentration of the odorant is at about 25-55 decismel units" because it is unclear as to what this concentration level relates to - e.g., is this the level of decismel units within each unit dosage or just a level of odorant in some initial odorant preparation from which such dosage units are prepared from?

Applicant's arguments have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicant argues that the odorant characteristics recited in the claims are well understood and suitable odorants are those that are capable of altering blood flow to the vagina via inhalation by a female. However, such odorants are not deemed to be well understood nor clearly delineated for the reasons set forth above. In addition, Applicant argues that other issued patents claim various odorants for methods of treatment. However, the this argument is not deemed persuasive for two reasons. Firstly, the merits of the instant application, including the Office actions of record, stand on their own. Secondly, this argument is not relevant to the instant teachings with respect to odorants having the unusual functional effects as instantly disclosed/claimed. Further, although Applicant argues that the specification states that "it is preferred that the subject individual is presented with the odorant at a superthreshold concentration (e.g., 25-55 decismel units), but not irritative level...", claim 10 - as drafted, is unclear for the reasons discussed above.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.



Christopher R. Tate
Primary Examiner, Group 1651